Late Stage Pre-Clinical Development of a Cirmtuzumab Based CAR T-cell for the Treatment of ROR1+ Hematological Malignancies

Grant Award Details

Late Stage Pre-Clinical Development of a Cirmtuzumab Based CAR T-cell for the Treatment of ROR1+ Hematological Malignancies

Grant Type: Late Stage Preclinical Projects

Grant Number: CLIN1-12865

Project Objective: The overall objective of this award is to file an IND for a "Cirmtuzumab"-based CAR T for treatment of ROR1+ hematological malignancies. The activities to be completed to meet this objective are, 1) manufacture GMP grade lentiviral vector meeting release criteria, sufficient for IND-enabling studies and the Ph1 trial; 2) Manufacture two clinical-scale lots of GMP-grade CAR T cells meeting release criteria; 3) prepare and file the IND.

Investigator:

Name:	Ezra Cohen
Institution:	University of California, San Diego
Type:	PI

Disease Focus: Blood Cancer, Cancer

Human Stem Cell Use: Adult Stem Cell

Award Value: $4,130,260

Status: Pre-Active

Grant Application Details

Application Title: Late Stage Pre-Clinical Development of a Cirmtuzumab Based CAR T-cell for the Treatment of ROR1+ Hematological Malignancies

Public Abstract:

Therapeutic Candidate or Device

We are developing ROR1 Chimeric Antigen Receptor (CAR) modified T-cells for the treatment of hematological and solid tumor cancers.

Indication

The target for our therapy are patients with chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL) and acute lymphoblastic leukemia (ALL).

Therapeutic Mechanism

Our lead candidate ROR1 CAR-T cell therapy modifies a cancer patient's T cells to recognize and attack tumors without the necessity for second or third signals. The ROR1 CAR-T cells we have developed at UCSD target and kill ROR1 expressing CSCs in in vitro and in vivo models of CLL and MCL. To advance this therapy into human clinical studies, we have assembled an experienced clinical development team and have adequate resources/infrastructure at UC San Diego to execute the proposed studies.

Unmet Medical Need

The CAR T-cell therapy that we are developing will be used to treat patients with difficult to treat hematological malignancies that are resistant to standard chemotherapies, have few therapeutic options, dire prognoses and represent a tremendous, global unmet medical need.

Project Objective

IND supporting preclinical activities completed

Major Proposed Activities

- Produce a clinical grade GMP lentiviral vector required to produce the patient modified CAR T-cells.
- Complete technology transfer to advance our research grade cell production process into a clinical grade GMP facility.
- Complete regulatory documents for submission to regulatory authorities including the UCSD IRB and FDA prior to phase I clinical study initiation.

Statement of Benefit to California:

California's cancer mortality rate has fallen by 27% since 1988, and the cancer incidence has declined 14%. Despite these improvements, nearly 1 out of every 2 Californians born today will develop cancer at some point in their lives, and 1 in 5 will likely die of the disease. In fact, in California, cancer represents the leading cause of mortality. The ROR1 CAR-T cell therapy we are developing will be a major addition to a physician's armamentarium for the treatment of these dire diseases.

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